IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8402

February 12, 2010

Bartle, C.J.

Judith M. Dahlka ("Ms. Dahlka" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Larry P. Dahlka, Ms. Dahlka's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Elias Kassab, M.D., F.A.C.C.[4] Based on an echocardiogram dated

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. The Show Cause Record also contains Part II of a Green Form signed by Linda J. Crouse, M.D., F.A.C.C., on May 30, 2002. By letter dated January 9, 2004, Ms. Dahlka advised the Trust that her claim should be based on the Green Form completed by Dr. Kassab. Therefore, we will consider Dr. Kassab claimant's attesting physician and refer to him as such.

February 19, 2002, Dr. Kassab attested in Part II of Ms. Dahlka's Green Form that she suffered from moderate mitral regurgitation and had an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $538,973.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Dr. Crouse, observed that claimant had "[m]oderate [mitral regurgitation], 4.05/15.53=26% of [left atrial] area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Crouse also found that claimant had "[m]ild [left atrial] enlargement; 5.34 cm in [four chamber] view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

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5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is among the complicating factors needed to qualify for a Level II claim. See id. § IV.B.2.c.(2)(b)ii).

In November 2005, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala determined that there was no reasonable medical basis for Dr. Kassab's finding of moderate mitral regurgitation. In support of this conclusion, Dr. Penkala explained: "[t]here is only trivial or physiologic [mitral regurgitation]. The traced 'RJAs' represent classic backflow." Dr. Penkala also found that claimant had a normal left atrial dimension and that there was no reasonable medical basis for Dr. Kassab's Green Form representation to the contrary. Specifically, Dr. Penkala stated that:

> I measured the [left atrium] to be normal at 32 mm [antero-posterior] and 50 mm [supero-inferior]. The technician measured the [left atrium] to be 3.85 cm from the [antero-posterior] dimension which is normal. It was measured to be 5.34 cm from the [supero-inferior]. This was however an overestimate of the true dimension extending from the annulus on a diagonal to a level below the [left atrial] roof. By all accounts the [left atrium] is normal in size.

Based on the auditing cardiologist's diagnosis of trivial or physiologic mitral regurgitation and a normal left atrial dimension, the Trust issued a post-audit determination denying Ms. Dahlka's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested

this adverse determination.[6] In contest, claimant submitted a report by Peter Mancini, M.D., F.A.C.C., based on her February 19, 2002 echocardiogram. In his report, Dr. Mancini opined that claimant suffered from moderate mitral regurgitation and an abnormal left atrial dimension. According to claimant, Dr. Mancini's findings "verify" that there is a reasonable medical basis for her claim.

Ms. Dahlka also submitted a declaration by Frank Miele.[7] Mr. Miele asserted that the Trust should have: (1) performed its clinical assessment on videotapes other than those duplicated by the Trust; (2) made allowances for degradation in the videotapes of the echocardiographic studies, as even the original videotapes show some degradation from what appears on the screen; (3) developed a protocol for data sharing that takes into account technological capabilities and

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Dahlka's claim.

7. Mr. Miele was retained by the law firms Napoli Kaiser Bern & Associates, LLP and Hariton & D'Angelo, LLP in connection with their representation of certain claimants. The law firms asked Mr. Miele to opine on the underlying science of echocardiography and how echocardiography equipment functions.

limitations; and (4) implemented a data duplication process that allows for significantly less degradation.[8]

Ms. Dahlka also argues that she has moderate mitral regurgitation because her RJA/LAA ratio is over 26% using the formula provided in the Cardiologist Training Course previously posted on the Trust's website. Finally, Ms. Dahlka submits that there is a reasonable medical basis for her cardiologist's report because the difference between the measurements in that report and the auditing cardiologist's report are insignificant.

The Trust then issued a final post-audit determination, again denying Ms. Dahlka's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Dahlka's claim should be paid. On May 30, 2006 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6341 (May 30, 2006).

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8. Mr. Miele also opined that the echocardiogram sequences identified by Joseph A. Kisslo, M.D., who was retained by the Trust in connection with its determination that certain claims previously determined to be payable might contain intentional material misrepresentations, do not accurately represent the true timing of events depicted in each respective study.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted its reply on July 24, 2006. Claimant submitted a sur-reply on September 18, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had an opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that there was no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Dahlka argues that the auditing cardiologist's findings are inconsistent with three other cardiologists who reviewed her echocardiogram.[10] In addition, Ms. Dahlka argues that the Trust focused its attention on the representations of Dr. Crouse, rather than Dr. Kassab, despite the fact that she had asked the Trust to disregard the Green Form completed by Dr. Crouse. Ms. Dahlka further argues that she had a third, independent cardiologist, Dr. Mancini, review her echocardiogram of attestation, and he concurred with Dr. Kassab's and Dr. Crouse's findings. Ms. Dahlka also explained that she did not submit the declaration of Mr. Miele as

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10. Ms. Dahlka also asserts that the difference in measurements may result from the different views used to review her echocardiogram. Specifically, Ms. Dahlka notes that the attesting cardiologist reviewed her echocardiogram in the apical four chamber view while the auditing cardiologist reviewed her echocardiogram in the parasternal long axis view. There is nothing in the Show Cause Record, however, to suggest that either the attesting physician or the auditing cardiologist used an inappropriate view in evaluating Ms. Dahlka's echocardiogram.

a diagnosis or physician's report; rather, she submitted it in support of her argument that the tape reviewed by the auditing cardiologist may be of poorer quality than the tape reviewed by her cardiologists because of degradation from copying. Finally, Ms. Dahlka submitted a copy of the auditing cardiologist's report and noted that it twice references that Dr. Penkala visually assessed claimant's echocardiogram, a claim that, according to Ms. Dahlka, the Trust denied.

In response, the Trust asserts that merely because the three cardiologists engaged by claimant to review her echocardiogram of attestation state that she has moderate mitral regurgitation and an enlarged left atrium does not establish that there is a reasonable medical basis for Dr. Kassab's Green Form representations. The Trust also explains that at audit, Dr. Penkala specifically reported that backflow, rather than true mitral regurgitation, was measured on Ms. Dahlka's echocardiogram of attestation. Finally, the Trust argues that Ms. Dahlka's claim cannot be supported by a reasonable medical basis where the measurements relied upon by Dr. Kassab and Dr. Mancini are based upon the echocardiogram conducted by Dr. Crouse, who purportedly reported backflow as true mitral regurgitation and over-estimated claimant's left atrial dimension by measuring on a diagonal.

In her sur-reply, claimant argues that the Trust did not present any evidence that the measurements on the

echocardiogram were incorrect. In addition, Ms. Dahlka suggests that Dr. Mancini is more qualified than Dr. Penkala and argues that the Trust incorrectly stated that Dr. Kassab did not prepare a report in connection with his review of her echocardiogram. Claimant further argues that the Trust cannot challenge her cardiologists' "over estimation" of her true dimension because, according to the New College Edition of the American Heritage Dictionary of the English Language, an estimate is "[a] judgment based upon one's impressions; an opinion," and it is impossible for the Trust to "say an opinion is wrong, it is a personal thing that is unique to each individual and effected by their training[,] knowledge and education ...." Next, claimant clarifies that, contrary to the Trust's characterization, she did not amend her Green Form and that "both were satisfactory and said the same thing." Claimant, as in her response to the Trust's statement of the case, also submits that Mr. Miele is an expert in echocardiographic technology rather than cardiology. Finally, claimant notes that her medical history indicates that she did not have a heart condition prior to her ingestion of Diet Drugs and that Dr. Kassab, in a letter to Warren J. Ringold, M.D., her family doctor, confirms that she had moderate mitral regurgitation and an abnormal left atrial dimension.[11]

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11. Claimant also identifies several statements by the Trust in a filing unrelated to her claim. Ms. Dahlka, however, does not (continued...)

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's representation that claimant suffered from moderate mitral regurgitation. Specifically, Dr. Vigilante found, in relevant part, that:

> There was evidence of mitral regurgitation. Mitral regurgitation was also documented on pulsed wave Doppler in the apical four chamber view. However, only mild mitral regurgitation was present .... I measured the RJA in those cardiac cycles in which the mitral regurgitation appeared most impressive. The RJA/LAA ratio was less than 17% even in those cardiac cycles in which the mitral regurgitation appeared most impressive. Most of the cardiac cycles in the apical four chamber and apical two chamber views demonstrated RJA/LAA ratios of less than 12%. The RJA measurement of 4.05 cm2 made by the sonographer was demonstrated on the echocardiogram tape. This was an inaccurate measurement which included a great deal of low velocity and non-mitral regurgitant flow.
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> * * *
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> ... An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.[12]

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11. (...continued)
explain how her exceptions to these statements entitle her to Matrix Benefits.

12. Dr. Vigilante also concluded that there was a reasonable medical basis for the attesting physician's finding that claimant (continued...)

In response to the Technical Advisor Report, claimant argues that there is a reasonable medical basis for her attesting physician's Green Form representation that she suffers from moderate mitral regurgitation because the difference between the Technical Advisor's determination and her cardiologists' determinations is "a minuscule variance." Ms. Dahlka also argues that the absence of mitral regurgitation in her November 19, 1997 echocardiogram establishes that her mitral valve regurgitation was caused by her ingestion of Diet Drugs. Finally, claimant argues that her expert, Dr. Mancini, met with her and reviewed the Technical Advisor Report. According to claimant, Dr. Mancini disagrees with Dr. Vigilante's assessment of Ms. Dahlka's mitral valve. In addition, Dr. Mancini confirmed to her that he did not rely on the sonographer's "flawed measurements."[13]

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12. (...continued)
had an abnormal left atrial dimension. Given our ultimate disposition regarding claimant's level of mitral regurgitation, however, we need not address whether claimant met her burden in proving that she had an abnormal left atrial dimension.

13. Ms. Dahlka originally included with her response to the Technical Advisor Report a letter dated July 30, 2007 from Dr. Mancini. Pursuant to Audit Rule 34, the Special Master advised Ms. Dahlka that Dr. Mancini's additional letter could not become part of the Show Cause Record. Ms. Dahlka submitted to the court directly an undated letter again attaching Dr. Mancini's July 30, 2007 letter. Pursuant to Audit Rules 34 and 35, there is no procedure by which Dr. Mancini's July 30, 2007 letter can become part of the Show Cause Record. Even if we were to consider his letter, however, it does not establish a reasonable medical basis for the attesting physician's representation that claimant has moderate mitral regurgitation.
(continued...)

After reviewing the entire Show Cause Record before us, we find that claimant has not established a reasonable medical basis for her claim. First, we disagree with claimant that the Trust did not present any evidence that the opinions of her cardiologists were incorrect. To the contrary, the Trust relied on the specific determinations of the auditing cardiologist, Dr. Penkala, including her conclusion that "[t]he traced 'RJAs' represent classic backflow."[14] Notably, Dr. Vigilante, following his review of the echocardiogram, additionally concluded that "[t]he RJA measurement of 4.05 cm2 made by the sonographer ... included a great deal of low velocity and non-mitral regurgitant flow."

Throughout the course of this litigation, we have rejected conclusions of cardiologists that are based on conduct beyond the bounds of medical reason. In PTO No. 2640, we explained that conduct "beyond the bounds of medical reason" can

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13. (...continued)
First, Dr. Mancini suggests that an evaluation of the level of mitral regurgitation includes an assessment of factors in addition to the RJA/LAA ratio as measured in any apical view. The Settlement Agreement, however, specifically requires that the level of mitral regurgitation be evaluated in any apical view using the RJA/LAA ratio. See Settlement Agreement § I.22. Second, Dr. Mancini opines that Ms. Dahlka's condition was caused by her ingestion of Diet Drugs. As explained infra, causation is not at issue in resolving Ms. Dahlka's claim.

14. For this reason as well, we reject claimant's argument that the Trust inappropriately considered the representations made by Dr. Crouse in its denial of her claim.

include (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Where, as here, neither claimant nor her cardiologists specifically contest the auditing cardiologist's and Technical Advisor's conclusions that the sonographer's measurements included backflow and low velocity flow, claimant fails to meet her burden of demonstrating that there is a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation.[15]

Further, claimant's assertion that she is entitled to Matrix Benefits because, as opined by her attesting physician, "[t]he patient clearly has evidence of underlying mitral valve regurgitation, most likely related to her previous Fen Phen

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15. For this reason as well, we reject claimant's argument that the Trust cannot challenge her cardiologists' "over estimation" because it is based on judgment. Moreover, we decline to accept Dr. Mancini's representations simply because he is, according to Ms. Dahlka, "much more experienced and qualified than Dr. Penkala."

intake," is erroneous. Causation is not at issue in resolving the claim presented here. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred.

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. As the Settlement Agreement clearly and unequivocally requires a claimant to prove that he or she suffers from at least moderate mitral regurgitation to receive Level II benefits, the court must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the cause of her mitral regurgitation was the ingestion of Diet Drugs is irrelevant to the issue before the court.

In addition, we reject claimant's argument that there is a reasonable medical basis for Dr. Kassab's representation that claimant suffers from moderate mitral regurgitation because the difference between the Technical Advisor's determination and

her cardiologists' determinations is only "minuscule." Based on the Singh grading system, the Settlement Agreement provides the basis for determining a claimant's level of mitral regurgitation. The concept of inter-reader variability is encompassed in this standard. See PTO No. 6824 at 10 (Dec. 29, 2006). In this instance, the representations by claimant's cardiologists cannot have a reasonable medical basis where the Technical Advisor concluded that claimant had only mild mitral regurgitation. Specifically, Dr. Vigilante found that "[t]he RJA/LAA ratio was less than 17% even in those cardiac cycles in which the mitral regurgitation appeared most impressive. Most of the cardiac cycles in the apical four chamber and apical two chamber views demonstrated RJA/LAA ratios of less than 12%." In addition, Dr. Vigilante noted: "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."[16] We cannot ignore Dr. Vigilante's findings, which identify precisely

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16. We also reject claimant's argument that the auditing cardiologist was unable to accurately assess Ms. Dahlka's level of mitral regurgitation as a result of videotape degradation. Although Mr. Miele opines in his declaration that videotape degradation may account for inaccurate echocardiographic interpretations by the Trust's cardiologists, the declaration is not specific to Ms. Dahlka, and she does not specifically identify how tape degradation affected Dr. Penkala's interpretation of her echocardiogram. Indeed, the Technical Advisor specifically noted that "[t]his echocardiogram tape was interpretable. This was a fair quality study with the usual echocardiographic views obtained."

claimant's level of mitral regurgitation. Adopting claimant's argument on inter-reader variability would expand the range of moderate mitral regurgitation and allow a claimant to recover Matrix Benefits even if his or her level of regurgitation is well below the threshold established in the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, we disagree with claimant that it was improper for Dr. Penkala visually to assess Ms. Dahlka's echocardiogram. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for Dr. Kassab's representation that Ms. Dahlka suffers from moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Dahlka's claim for Matrix Benefits and the related derivative claim submitted by her spouse.